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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

10

DATE MAILED: 03/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/596,086

Applicant(s)
BIEDERMANN et al.

Examiner
Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 27, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Claims 1-31 are present in the application.

Election/Restriction

1. Applicant's election of Group I in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-31 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction requirement. The Markush group represented by the term G has variably different definitions, rendering the claims clearly improper.

Information Disclosure Statement

3. The information disclosure statement filed January 4, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the first citation under the heading OTHER DOCUMENTS is **incomplete and not in the English language**. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on

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the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

It is also noted that there are three Chemical Abstracts listed under the heading OTHER DOCUMENTS where there is no indication what the chemical abstract number is and it is not known what is meant by the Rote Liste, 1997 which is the last citation under the heading OTHER DOCUMENTS.

Specification

4. The abstract of the disclosure is objected to because the content of the abstract is of different scope than the claims. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Evidence involving a single compound and two types of cancer was not found sufficient

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to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds *In re Buting* 163 USPQ 689. The remarkable advances in chemotherapy have seen the development of specific compounds to treat specific types of cancer. The great diversity of diseases falling within the "tumor" category means that it is contrary to medical understanding that any agent (let alone a genus of thousands of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5 and 7-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 1 (and claims dependent thereon) recites pyridylalkane, pyridylalkene and pyridylalkine amides of the **general** formula (I). Pyridylalkane, pyridylalkene and pyridylalkine amides refers to more than one, thus giving the impression of a mixture rather than a single compound. A formula is not general when all of the variables are defined. Deletion of "general" is suggested.
- b) Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed

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invention. See MPEP § 2173.05(d). See the definition of R¹, R², R³, R⁴, R⁵, A, D, R⁸, R⁹, R¹², Ar¹, Ar² and the list of substituents for the aromatic ring systems in the substituents of R¹, R², R³, R⁴, R⁵, R⁸, R⁹, R¹⁰, R¹¹, R¹², Ar¹ and Ar².

- c) Claims 1-4, 7 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the variables G1, G2, G3, G4, G5 or G6, which are not defined in the claim.
- d) Claims 1-4, 7 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the definitions of the variables G¹, G², G³, G⁴, G⁵ or G⁶, because there are no variables G¹, G², G³, G⁴, G⁵ or G⁶ in formula (I).
- e) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are

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pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claims 1 and 2 (and claims dependent thereon) recite the broad recitation the cis- and trans-isomers as well as E- and Z-isomers of the above defined compounds, and the claim also recites especially in the case that A is a cyclopropane ring or D contains one or more double bonds which is the narrower statement of the range/limitation.

- f) Claim 2 contains a capital letter other than the one at the beginning of the claim.

See the definition of R² and A.

608.01(m) Form of Claims [R - 3]

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). ** Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

- g) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent

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Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 2 recites the broad recitation anellated bi- and tricyclic aromatic or partially hydrated carbocyclic ring systems with 8 to 18, and the claim also recites especially with up to 16 ring atoms which is the narrower statement of the range/limitation. See the definition of R^8 , R^9 , R^{12} and the grouping $=CR^8R^9$.

- h) Claims 3-5 (and claims dependent thereon) recites compounds of the **general** formula (I). Compounds refers to more than one, thus giving the impression of a mixture rather than a single compound. A formula is not general when all of the variables are defined. Deletion of "general" is suggested.

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- i) Claim 3 contains a capital letter other than the one at the beginning of the claim.
See the definition of A and the list of substituents for the aromatic ring systems of R^1 , R^3 , R^8 , R^9 , R^{10} , R^{11} , R^{12} , Ar^1 and Ar^2 , etc.
- j) Claim 3 contains a period at the end of the list of substituents for the aromatic ring systems of R^1 , R^3 , R^8 , R^9 , R^{10} , R^{11} , R^{12} , Ar^1 and Ar^2 , etc.
- k) Claim 4 contains a capital letter other than the one at the beginning of the claim.
See the list of substituents for the aromatic ring systems of R^1 , R^3 , R^8 , R^9 , R^{10} , R^{11} , R^{12} , Ar^1 and Ar^2 , etc.
- l) Claim 5 recites the limitation "one or two methylene units" in the definition of D.
There is insufficient antecedent basis for this limitation in the claim.
- m) Claim 5 recites the limitation "tetrahydrobenzocycloheptenyl and hydroxytetrahydrobenzocycloheptenyl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.
- n) Claim 5 is vague and indefinite in that it is not known what is meant by the definition of G where dibenzylaminocarbonylamino is listed twice. See page 192, last paragraph.
- o) Claim 7 (and claims dependent thereon) is vague and indefinite in that the definitions of R^1 , R^2 , A and k "have the meanings given above", however, they are not defined within the claim. Proper direction to the definition of R^1 , R^2 , A and k is required.

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- p) Claim 7 (and claims dependent thereon) recites the limitation "reactive derivatives" on page 195 and 197. There is insufficient antecedent basis for this limitation in the claim.
- q) Claim 7 (and claims dependent thereon) is vague and indefinite in that the definitions of D, G and R³ "are defined above", however, they are not defined within the claim. Proper direction to the definition of D, G and R³ is required.
- r) Regarding claim 7 (and claims dependent thereon) the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See the last paragraph on page 195 and the first paragraph on page 197.
- s) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for

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example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation anhydrides acid halides, and the claim also recites especially acid chlorides which is the narrower statement of the range/limitation.

- t) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd.

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Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation suitable solvent, and the claim also recites preferably inert solvent which is the narrower statement of the range/limitation.

- u) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation a reaction temperature, and

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the claim also recites especially between -40°C and 180°C which is the narrower statement of the range/limitation.

- v) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation a reaction temperature, and the claim also recites preferably between -10°C and 130°C which is the narrower statement of the range/limitation.

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- w) Claim 7 (and claims dependent thereon) is vague and indefinite in that it is not known what is meant by "suitable nucleofuge".
- x) Claim 7 (and claims dependent thereon) is vague and indefinite in that it is not known what is meant by the phrase "according to the above definition" in the definition of G3a on page 196. What definition?
- y) Claim 7 (and claims dependent thereon) is vague and indefinite in that the definitions of m, n, R⁸, R⁹ and R¹⁰ "are defined as above", however, they are not defined within the claim. Proper direction to the definition of m, n, R⁸, R⁹ and R¹⁰ is required.
- z) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are

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pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation the reaction, and the claim also recites preferably takes place in the presence of bases as named above which is the narrower statement of the range/limitation.

- aa) Claim 7 (and claims dependent thereon) is vague and indefinite in that it is not known what is meant by the phrase "bases as named above" in the first paragraph on page 197. What definition?
- ab) Regarding claim 7 (and claims dependent thereon), the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See the first paragraph on page 197.
- ac) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can

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render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation a reaction temperature, and the claim also recites especially between 0°C and 180°C which is the narrower statement of the range/limitation.

- ad) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for

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example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation a reaction temperature, and the claim also recites preferably between 20°C and 130°C which is the narrower statement of the range/limitation.

- ae) Claim 7 (and claims dependent thereon) is vague and indefinite in that it is not known what is meant by the phrase “according to the above definition” in the definition of G4 to G6 on page 197. What definition?
- af) Claim 7 (and claims dependent thereon) is vague and indefinite in that the definitions of m, Y, Z, R⁸, R⁹, R¹⁰, R¹², Ar¹, Ar², and optionally the group NR⁸R⁹ “have the above meanings”, however, they are not defined within the claim. Proper direction to the definition of m, Y, Z, R⁸, R⁹, R¹⁰, R¹², Ar¹, Ar², and optionally the group NR⁸R⁹ is required.
- ag) “Derivative” in claim 7 (and claims dependent thereon) implies more than what is positively recited. See the sixth line from the bottom of page 197.
- ah) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the

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patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation reaction, and the claim also recites preferably in the presence of auxiliary bases which is the narrower statement of the range/limitation.

- ai) Claim 7 (and claims dependent thereon) is vague and indefinite in that it is not known what is meant by the phrase "according to the definition G4b" in the last line of page 197. What definition?
- aj) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the

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patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation carbonyl group transmitter, and the claim also recites preferably with a bistrichloromethy carbonate which is the narrower statement of the range/limitation.

- ak) Claim 7 is vague and indefinite in that it is not known what is meant by "bistrichloromethy carbonate" on page 198.
- al) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent

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Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat.

Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation reaction, and the claim also recites especially in an absolute, inert solvent in the presence of a tertiary organic amine as an auxiliary base which is the narrower statement of the range/limitation.

- ak) Claim 7 (and claims dependent thereon) is vague and indefinite in that it is not known what is meant by "absolute", inert solvent.
- am) Claim 7 (and claims dependent thereon) is vague and indefinite in that the definitions of R^8 and R^9 , and optionally the group NR^8R^9 "have the meanings according to the above definitions", however, they are not defined within the claim. Proper direction to the definition of R^8 and R^9 , and optionally the group NR^8R^9 is required.

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- an) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation temperature, and the claim also recites especially between -40°C and 50°C which is the narrower statement of the range/limitation.
- ao) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the

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patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation temperature, and the claim also recites preferably between 0°C and 30°C which is the narrower statement of the range/limitation.

- ap) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language

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is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation temperature between 0°C and 150°C, and the claim also recites preferably between 20°C and 120°C which is the narrower statement of the range/limitation.

- aq) Claim 7 (and claims dependent thereon) is vague and indefinite in that it is not known what is meant by the phrase "according to the definition G4b" on page 198. What definition?
- ar) Claim 7 (and claims dependent thereon) is vague and indefinite in that the definition of R⁸ "has the meanings defined above", however, they are not defined within the claim. Proper direction to the definition of R⁸ is required.
- as) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the

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patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation reaction, and the claim also recites preferably in absolute, inert solvent which is the narrower statement of the range/limitation.

- at) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language

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is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation temperature, and the claim also recites especially at a reaction temperature which can vary in the range of -20°C and 150°C which is the narrower statement of the range/limitation.

- au) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim,

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and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 7 (and claims dependent thereon) recites the broad recitation reaction temperature which can vary in the range of -20°C and 150°C, and the claim also recites preferably at 20°C and 100°C which is the narrower statement of the range/limitation.

- av) Claims 8 and 9 (and claims dependent thereon) are substantial duplicates of claims 1 and 2, as the only difference is a statement of intended use which is not given material weight. Note *In re Tuominen* 213 USPQ 89.
- aw) Claims 10, 29 and 31 (and claims dependent thereon) provide for the use of the compounds of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
- ax) Claims 11-27 and 30 (and claims dependent thereon) are vague and indefinite in that the terminology “a medicament” does not clarify whether the claim is limited to a compound, composition, or even complex composition.

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- ay) Claim 28 is vague and indefinite in that the terminology “a substance or substance mixture” does not clarify whether the claim is limited to a compound, composition, or even complex composition.
- az) Claim 11 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by “one or more active ingredients”.
- ba) Claim 14 is vague and indefinite in that it is not known what is meant by “medicaments”.
- bb) Regarding claim 15, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- bc) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for

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example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. Claims are pending in the application.. 1949). In the present instance, claim 23 recites the broad recitation dosage unit, and the claim also recites preferably, 0.01 to 100 mg, in a preferred manner 1 to 10 mg, which is the narrower statement of the range/limitation.

- bd) Claim 23 recites the limitation "especially 1, 2, 5, 10, 20, 25, 30, 50, 75, 100, 200, 300, 400, 500, 600 or 800 mg" in the dosage unit. There is insufficient antecedent basis for this limitation in the claim.
- be) Claims 28 and 30 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by "cytostatic agent or immunosuppressive agent".
- bf) Claims 10-31 are vague and indefinite in that the claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the diseases in connection with cancerostatic or cytostatic anti-proliferative or immunosuppressive treatment or inhibition of abnormal cell growth and/or preventing the formation of metastases. It is unclear which diseases are capable of being mediated by cancerostatic or cytostatic anti-proliferative activity. Determining whether a given disease responds or does not respond to such an inhibitor will involve undue experimentation. Suppose that a given drug,

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which has inhibitor properties *in vitro*, when administered to a patient with a certain disease, does not produce a favorable response. One can not conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment? Thus, how many patients need to be treated? If “successful treatment” is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? The optimum route of administration can not be predicted in advance. Should our drug be given as a bolus *iv* or in a time release *po* formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

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C. It may be that our specific drug, while active *in vitro*, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many different structurally related inhibitors must be tried before one concludes that a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of whom are inhibitors *in vitro*, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property which the second drug is capable. It is common for a drug, particularly in tumor growth, to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor *XXY* agonist or antagonist, but upon further experimentation shown to effect a variety of biological targets. In fact, the development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

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E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy which are not themselves effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 7-11, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishihara et al., Chem. Pharm Bull. Ishihara teaches the compounds, compositions, process of preparing and method of use of the instant invention where R¹, R² and R³ are hydrogen, A is -CH=CH-, D is (CH₂)₅ and G is -N(C₂H₅)-CH₂-phenyl. See example 3n.

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Claim Objections

8. Claims 10, 12, 23, 25, 26, 29 and 31 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternative. See MPEP § 608.01(n).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
March 4, 2002